SUMMARY OF INTERVIEW

Exhibits and/or Demonstrations

None

Identification of Claims Discussed

32-41, 43, 44, 46, 53-57, and 59, i.e., all the pending claims

Identification of Prior Art Discussed

Evans (USP 5,702,361); Okada (USP 5,202,352)

Proposed Amendments

Applicants suggested amending claim 32 to recite that the biologically active material is separate and distinct from the other two components in the system.

Principal Arguments and Other Matters

Applicants argued that the remarks presented in the response the Office of April 4, 2006 made it clear that the biologically active material is a separate and distinct component from the vaso-occlusive precursor composition and the mechanical occlusive device. However, the Examiner requested that this distinction be made explicit in the claims. Applicants further argued that Okada does not teach or suggest the use of polymer precursors or dissolved polymeric material for direct injection into a human. Instead, the reference teaches the use of dissolved polymeric material for the formation of microspheres.

Results of Interview

Though agreement was not reached, the Examiner suggested that the proposed amendment would potentially overcome the rejections over Evans. The Examiner would further review Okada and related references to weigh the arguments.

REMARKS

Applicants sincerely thank the Examiner for the courtesy he extended Applicants' representative during the telephonic interview of November 27, 2006.

Applicants have amended claims 32, 41, 44 and 55. No new claims are added, nor any claims deleted. Accordingly, Claims 32-41, 43, 44, 46, 53-57, and 59 remain pending.

Claim 32 has been amended to further clarify the claimed dissolved composition and the system. The present amendments add no new matter and are fully supported by the specification as initially filed. Claims 41, 44, and 55 are amended to correct minor typographic errors, as pointed out by the Examiner on page 2 of the Office Action. Support for the amendment to claim 32 is found throughout the specification, where the biologically active component is described separately from the vaso-occlusive precursor composition or the mechanical occlusive device. *See*, for example,

- page 6, lines 16-18, where the polymer-forming or dissolved polymeric, biodegradable materials are listed as a separate component of the mixture than the at least one biologically active component;
- page 7, lines 5-22, where the suitable polymers are disclosed, and page 7, line 24 to page 11, line 3, where the suitable biologically active components are disclosed; and
- page 4, line 3 to page 5, line 13, and page 13, line 13 to page 14, line 15, where mechanical occlusive devices are listed;

where there is no overlap between the three components.

Applicants have considered all of the objections and rejections raised in the Office Action of September 18, 2006 and respond fully below.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 41, 44, and 46 stand rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite.

Applicants respectfully submit that the amended claim 41 does not reference "other" proteins or "full" or "partial" DNA constructs, and in the amended claim 44 the erroneous period is replaced with a comma, and "and viral" is deleted.

Applicants respectfully traverse the rejection of claim 46. Applicants respectfully submit that those of ordinary skill in the art recognize that a polypeptide encompasses all molecules in which two or more amino acids are joined together by a peptide bond. For example, a dipeptide, tripeptide, or octapeptide are all polypeptides. The definition of polypeptide also encompasses much larger molecules, e.g., proteins, which have biological function, for example, as catalysts, receptors, transport molecules, etc. Claim 46 is intended to encompass both polypeptides that are short, but still have therapeutic effect, and those that are long enough and have independent biological function to be classified as proteins.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 112, First Paragraph

Claim 41 stands rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants have amended claim 41 and have removed the subject matter that the Examiner found objectionable. In view of these amendments, Applicants respectfully submit that the rejection of claim 41 under 35 U.S.C. § 112, first paragraph, is now moot.

Rejections under 35 U.S.C. § 102(e)

Claims 32, 33, 38, 39, 53-55, and 59 stand rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by Evans (USP 5,702,361). Applicants respectfully traverse.

In response submitted on June 29, 2006 to the Office Action of April 4, 2006 ("the previous response"), Applicants submitted that Evans does not teach the presence of a separate biologically active component, and clearly stated that in the present claims the biologically active component is separate and distinct from the polymer-forming or dissolved polymeric, biodegradable material. *See*, for example, page 6 of the previous response. In the present Office Action the Examiner states that he finds Applicants arguments unpersuasive because there is allegedly no reason "that items 'a' and 'b' cannot be the same compound, or that items 'a' and 'b' cannot represent different fractions of a pool of a given compound." Office Action, page 7.

Applicants have amended claim 32 to explicitly recite that the biologically active component *is not* the vaso-occlusive precursor composition or the mechanical occlusive device.

Therefore, the amended claim 32 is directed to a system comprising three separate and distinct components: a vaso-occlusive precursor composition, a biologically active component, and a mechanical occlusive device.

Applicants respectfully submit that because at least one element of claim 32 is not present in Evans, the cited reference does not anticipate claim 32. Because the remaining claims incorporate, either directly or indirectly, the limitations of claim 32 by reference, Applicants respectfully submit that Evans does not anticipate any of the remaining claims either. In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 102(e).

Rejections under 35 U.S.C. § 103(a)

Evans in view of Slepian

Claims 32 and 34-36 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Evans in view of Slepian (USP 5,634,946). Applicants respectfully traverse.

The difference between Evans and the presently claimed subject is discussed above. As discussed in the previous response, Slepian teaches a method similar to that of Evans, except with different polymeric materials. Slepian does not teach the presence of a third and separate biologically active component. Therefore, the references, either alone or in combination, fail to disclose at least one limitation of the pending claims, namely the biologically active component.

In addition, Applicants respectfully submit that Evans and Slepian, either alone or in combination, fail to motivate or provide expectation of success for adding a biologically active component to the polymeric material taught by these references.

Okada

Claims 32- 41, 43, 44, 46, and 53-59 stand rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Okada (USP 5,202,352) in view of Cragg 1 (USP 6,558,367), Whalen (USP 6,531,111), Cragg 2 (USP 6,146,373), Greff (USP 6,015,541), Murayama (USP 5,891,192), and Sawhney (USP 6,818,018). Applicants respectfully traverse this rejection as well.

Okada is directed to the preparation of an intravascular embolizing agent, which is a mixture of an intravascular embolizing substance and an angiogenesis-inhibiting substance.

Okada discloses three ways that the two substances can be combined to form the agent as follows:

> According to the present invention, the intravascular embolizing agent may be in the form of [1] *a mere mixture* of the angiogenesis-inhibiting substance with the above-described intravascular embolizing substance or [2] in the form of an agent prepared by allowing the angiogenesis-inhibiting substance to *be included in the inner structure* of the intravascular embolizing substance or [3] *adsorbed on the surface* of the intravascular embolizing substance by a per se known method, the latter is preferable. (Emphasis added.)

Column 8, lines 12-20.

The bulk of the disclosure of Okada is directed describing the preparation of the intravascular embolizing agent by the latter two methods. For example:

- Column 8, lines 21-37 discloses adsorption using ion-exchange resin.
- Column 8, line 58 to column 9, line 61 discloses forming microspheres for including the angiogenesis-inhibiting substance.
    - Column 9, lines 22-24 states "the organic solvent is evaporated to prepare microspheres of intravascular embolizing agent".
    - Column 9, lines 45-47 states "followed by solidification to give microspheres of intravascular embolizing agent".
    - Column 9, lines 59-61 states "followed by the same solidification process as mentioned above to give an intravascular embolizing agent".
- Examples 1 and 6 are directed to the formation of microspheres (abbreviated as msp).
- Examples 2-5 and 7 are directed to the injection of the microspheres.

As for the "mere mixture" of the two substances, the "above-described intravascular embolizing substances" that can be mixed with the angiogenesis-inhibiting substance are listed at column 7, line 15 to column 8, line 4. Applicants respectfully submit that none of the listed intravascular embolizing substances is a polymer-forming, or dissolved polymeric, biodegradable material. They are all polymers. Okada does disclose that the intravascular embolizing substance could be dissolved in organic solvents "for example, dichloromethane, chloroform, ethyl acetate, isopropyl ether, etc.", but for the purposes of preparing a colloid or spray-dried composition, and not for direct injection into a patient (column 8, line 58 to column

9, line 15). Further, Applicants respectfully submit that none of these organic solvents are pharmaceutically acceptable for direct injection into a human patient.

In addition, the only "mere mixture" disclosed in Okadais a mixture of one of two angiogenesis-inhibiting substances with lipiodol, which is an iodized poppy seed oil. See, for example, column 10, lines 62-66, and Example 8. (Applicants note that Example 8 is directed to mixtures with "lipidol." However, given the above-referenced disclosure on column 10, and the fact that "lipidol" is a non-existent substance, Applicants believe that the reference to "lipidol" in Example 8 is a typographic error.) Lipiodol is neither a polymer nor a polymer precursor.

Thus, Applicants respectfully submit that Okada does not disclose, teach, or suggest, nor does it provide the motivation to practice, a system comprising a mixture of a polymer-forming, or dissolved polymeric, biodegradable material with a biologically active compound, and a device.

Applicants respectfully further submit that the other references do not disclose subject matter that would overcome Okada's failure to teach or suggest the claimed subject matter. Cragg 1, Whalen, Cragg 2, Greff, Murayama, and Sawhney are directed to the use of various embolizing agents. None of the disclosed embolizing agents is a polymer-forming, or dissolved polymeric, biodegradable material.

In view of the above, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103(a).

CONCLUSION

Applicants have amended claim 32. Claims 32-41, 43, 44, 46, 53-57, and 59 remain pending. Applicants have endeavored to respond to all of the Examiner's rejections and objections raised in the Final Office Action of April 4, 2006. Applicants respectfully submit that the claims as amended herein are patentable and should be passed to issue. A notice to that effect is respectfully requested.

No fee is believed due with respect to this response. If this is incorrect, please charge any required fees, including any fees for extension of time, to Deposit Account No. 50-1105. Applicants invite the Examiner to call the undersigned if any issue can be resolved through a telephonic discussion.

Respectfully submitted,

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